#### REMARKS

Claims 71-87 and 103-105 are now pending in the above-referenced patent application.

Applicants respectfully request further consideration of these claims, in view of the amendments set forth above and the following remarks.

### **Amended Claims**

Claim 71 has been amended. Support for this amendment can be found throughout the specification, including for example at page 9, lines 13-21.

No new matter has been added.

# Rejection Under 35 U.S.C. § 102(a)

The Examiner rejected claims 71-72, 74, 77, 78, 84 and 103-105 under 35 U.S.C. 102(a) as being anticipated by PCT Application WO 98/43558 A1 ("Starling"). Applicants respectfully traverse the rejection.

Independent claim 71 describes a prosthetic material including a scaffold having interconnecting, uniformly shaped pores, and an ingrowth matrix within the pores, wherein the ingrowth matrix comprises a concentration gradient of a material and is adapted to promote ingrowth of tissue in the scaffold. Varying concentrations within the ingrowth matrix are designed to perform specific functions. An exemplary description of this feature states:

More specifically, one material is present throughout the ingrowth matrix 27, but in various concentrations between a core of the ingrowth matrix 27 and an outermost surface of the ingrowth matrix 27. Like the layers 28, 30 and 32 in the multilayered embodiment, the concentration gradient 38 is present throughout the transmural ingrowth channels 34 and/or pores 36. Furthermore, varying concentrations within the ingrowth matrix 27 are designed to perform specific functions. For example, different cells can be sensitive to different concentrations, therefore a concentration gradient allows multiple ingrowth options within one matrix 27.

Specification, page 9, lines 13-21. Applicants respectfully submit that Starling lacks, among other things, a teaching or suggestion of the pores and ingrowth matrix as claimed.

Applicants respectfully submit that Starling fails to teach or suggest several features of the rejected claims, including interconnecting, uniformly shaped pores and an ingrowth matrix

having a concentration gradient of a material that is adapted to promote ingrowth of tissue in the scaffold where varying concentrations within the ingrowth matrix are designed to perform specific functions. Starling teaches calcium phosphate microcarriers and microspheres for use, among other things, as implantable materials useful for biomedical implants. The microspheres can be aggregates of hollow microspheres having dense walls. See Starling Figure 1.4. The microshperes can be used as carriers of growth factors and pharmaceutical agents. See Starling, page 13, lines 11-13. The growth factor can either be coated on the microsphere, impregnated within the wall of the microsphere, or be located in a central cavity of the microsphere. See Starling, page 13, lines 17-24. The wall of the microsphere can be replaced by tissue in-growth as material within the wall resorbs. See Starling, page 13, lines 26-28. Applicants respectfully submit that the pores of Starling are not interconnected, and that the growth factor, to the extent it may be interpreted as an ingrowth matrix, does not have varying concentrations designed to perform specific functions as claimed in independent claim 71. The pores of Starling, whether as the centers of the hollow microspheres, or the interstices between microspheres, are not interconnected. See figure 1.4. Additionally, the ingrowth matrix described in Starling does not have varying concentrations designed to perform specific functions. While there may or may not be varying concentrations, Starling is silent as to any design that would involve one concentration having any specific function over another.

Claims 72, 74, 77, 78, 84, and 103-105 depend on and incorporate all of the limitations of independent claim 71.

For at least the reasons discussed herein above, Applicants respectfully submit that claims 71-72, 74, 77, 78, 84, and 103-105 are neither taught nor suggested by Starling.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 102 are respectfully requested.

# Rejections Under 35 U.S.C. § 103(a) (Starling)

The Examiner rejected claims 71-87 and 103-105 under 35 U.S.C. 103(a) as being unpatentable over Starling.

Applicants respectfully traverse the rejection.

The law is clear that "to establish a prima facie case of obviousness, all the claim limitations must be taught or suggested by the prior art." See MPEP Sec. 2143.03; In re Royka,

180 USPQ 580 (CCPA 1974). As discussed above, however, technically and commercially significant features of the presently-claimed inventions are <u>not</u> taught or suggested by the prior art.

As discussed above, Applicants respectfully submit that Starling fails to teach or suggest several features of the rejected claims, including interconnecting, uniformly shaped pores and an ingrowth matrix having a concentration gradient of a material that is adapted to promote ingrowth of tissue in the scaffold where varying concentrations within the ingrowth matrix are designed to perform specific functions. For at least this reason, Applicants assert that independent claim 71 is not obvious over Starling.

Additionally, claim 82, which depends upon and incorporates all of the limitations of claim 71, requires that the scaffold have interconnecting, helically oriented channels within the scaffold. Starling does not teach this feature. Starling does teach a thread of a bone screw having a helical design. However, this is what is claimed. The screw thread disclosed in Starling does not constitute interconnecting helical channels IN the scaffold of the prosthesis, but rather a single helical feature on the outer surface of a device. For at least this reason, claim 82 is not obvious over Starling.

Claims 72-81, 83-87 and 103-105 depend directly or ultimately from independent claim 71. Applicants respectfully submit that claims 72-81, 83-87 and 103-105 are patentable over Starling for at least the reasons discussed herein above for the patentability of claim 71, in addition to reasons related to the additional subject matter recited in each.

Reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a) are respectfully requested.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Examiner is hereby authorized to charge the fees required in connection with this Amendment to Deposit Account No. 13-2546, in accordance with the Transmittal submitted herewith. The Examiner is also authorized to debit any other fees required in connection with this application, or to credit any overpayment of fees in connection with this application to Deposit Account No. 13-2546.

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Respectfully submitted,

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